REMARKS

Claims 1-17 are pending in the instant application. Claims 6, 11-14, 16 and 17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants by this amendment. Claims 1-5, 7-10 and 15 have been rejected. Claim 1 and 15 have been amended. Support for these amendments can be found in the specification at page 32 and 33 and Example 1. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed July 23, 2003. Thus, Applicants have canceled non-elected claims 6, 11-14, 16 and 17 without prejudice. However, in light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Specification

The specification has been amended to capitalize and to include generic terminology next to all trademarks.

The specification has also been amended to delete the phrase

http://" from embedded hyperlinks.

No new matter is added by these amendments and entry is respectfully requested. Withdrawal of the objections to the specification is respectfully requested in light of these amendments.

III. Rejection of Claims 1-5, 7-10 and 15 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-5, 7-10 and 15 have been rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, as the Examiner suggests that the claimed invention lacks patentable utility. The Examiner suggests that the specification does not disclose a connection between the presence of SEQ ID NO:8 and ovarian cancer. Further, the Examiner suggests that demonstration of expression of a sequence in a specific tissue type cannot be translated to mean that the sequence is necessarily a marker for cancer in that tissue.

Applicants respectfully traverse these rejections.

It appears that these rejections are based upon an improper characterization of the teachings of the instant specification.

Contrary to the Examiner's suggestion, the nexus between SEQ ID NO:8 expression and ovarian cancer is taught in Example 1 of the specification wherein mRNA subtraction assays demonstrative

of differential expression of the OSNAs including SEQ ID NO:8 in cancer tissue versus normal tissue is described. In these experiments OSNAs including SEQ ID NO:8 were first examined for degree of specificity for the tissue of interest. mRNA subtractions assays exhibiting differential expression of the OSNAs in cancer samples as compared to normal tissue were then performed. The high level of tissue specificity, plus differential mRNA expression in matching samples versus normal samples, is indicative of SEQ ID NO:1 through SEQ ID NO:76 being a diagnostic marker for cancer. Accordingly, these teachings of the specification make clear that identification of SEQ ID NO:8 as a cancer marker is not based simply on tissue specificity, but also on mRNA differential expression in cancer samples.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:8 as having a high level of tissue specificity, plus mRNA differential expression in cancer samples as compared to normal samples constitutes a pharmacological activity relevant to the asserted use as a

diagnostic for ovarian cancer, thus satisfying the utility requirements of 35 U.S.C. § 101 and 35 U.S.C. § 112.

Withdrawal of these rejections is therefore respectfully requested.

IV. Rejection of Claims 1-5, 7-10 and 15 under 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 1-5, 7-10 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such as way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the Examiner suggests that the specification lacks deposit information for the deposit of the plasmid deposited with the ATCC as discussed at page 115 through 118 of the specification for SEQ ID NO:8. The Examiner suggests that amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required along with a statement verifying that the deposit was made under the Budapest Treaty.

Thus, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification to include

the complete name and address of the depository. With respect to the deposit date, Applicants respectfully direct the Examiner to the Table beginning at page 117 which includes in column 6 both the ATCC Number for the deposit and the deposit date. Applicants are also submitting herewith a statement by an Attorney of record that the invention will be irrevocably and without restriction released to the public upon issuance of a patent.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

V. Rejection of Claims 1-5, 7-10 and 15 under 35 U.S.C. § 112, first paragraph - Lack of Written Description

Claims 1-5, 7-10 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner suggests that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner suggests that the specification does not describe or disclose nucleic acid molecules which hybridize or are capable of hybridizing with the sequence of SEQ ID NO:8. The Examiner also suggests that the specification does not

describe or disclose any functionality of the undisclosed nucleic acid molecules associated with a sequence having at least 60% identity to SEQ ID NO:8.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete reference to hybridizing sequences. Further, Applicants have amended the claims to clarify the functionality of sequences sharing 80% identity to SEQ ID NO:8 as being differentially expressed in ovarian cancer. Support for this amendment is provided in the specification at page 32, lines 20-26, and page 33, lines 1-4 and Example 1 wherein methods for identifying nucleic acid sequences differentially expressed in ovarian cancer are set forth.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph, is respectfully requested in light of these amendments.

VI. Rejection of Claims 1-5 and 15 under 35 U.S.C. § 112, second paragraph

Claims 1-5 and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Examiner suggests that claims 1-5 and 15

are vague and indefinite because they claim more than was elected.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to be drawn to the elected subject matter of SEQ ID NO:8, a subsequence of SEQ ID NO:8, namely SEQ ID NO:7, or a polypeptide encoded thereby, SEQ ID NO:82.

Claims 1-5 are also suggested to be vague and indefinite in reciting "selectively hybridizes" because the term is not clearly defined at pages 15-17. Applicants respectfully disagree as the definitions provided throughout the specification are believed to be clear and definite to the skilled artisan in accordance with MPEP 2173. However, as discussed in Section V, supra, this phrase has been deleted from the claims, thus mooting this rejection.

Claim 15 is suggested to be vague and indefinite because the "means" for determining the presence of the nucleic acid as required by the kit are not clearly defined in the specification or claims. Applicants respectfully disagree.

Contrary to the Examiner's suggestion, multiple means for determining the presence of a nucleic acid are taught in the specification. See, for example page 93, line 12, through page

94, line 10.

MPEP § 2173 is quite clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in that pertinent art at the time the invention was made. The content of the application in this case makes clear various means for detecting a nucleic acid in accordance with the claimed kits, thus meeting the requirements of 35 U.S.C. § 112, second paragraph. Further clarification in the claims is not required.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is respectfully requested in light of the above remarks and the amendments to the claims.

VII. Rejection of Claims 1-5, 7-10 and 15 under 35 U.S.C. § 102(a) and 102(e)

Claims 1-5, 7-10 and 15 have been rejected under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e) as being anticipated by Hillman et al. (U.S. Patent 6,135,941). The Examiner suggests that Hillman et al. disclose a nucleic acid sequence capable of hybridizing with the sequence of SEQ ID NO:8 and having 93.3% similarity to

SEQ ID NO:8.

Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner's characterization of the teachings of Hillman et al. The 93.3% similarity in Hillman et al. suggested by the Examiner is local similarity over a 691 nucleotide region of SEQ ID NO:8. The query match for the full length sequence of SEQ ID NO:8 with Hillman et al. only shows 41.6% similarity.

However, in an eanrest effort to advance the prosecution of this case, as discussed in Section V, supra, claim 1 has been amended to delete reference to hybridizing sequences. Further, the claims has been amended to clarify that the sequence must have at least 80% identity with respect to SEQ ID NO:8 and be differentially expressed in ovarian cancer. Since Hillman does not teach a sequence with these characteristics, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. 102(a) and 102(e) is therefore respectfully requested.

VIII. **Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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